

APPLICANT(S): DALTON, James T. et al.  
SERIAL NO.: 10/849,039  
FILED: May 20, 2004  
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#### Status of Claims

Claims 1-95 are pending in the application. Claims 1-20, 24-31, 35-37, 52-64, 68-75 and 79-81 have been rejected.

Claims 21-23, 32-34, 38-51, 65-67, 76-78 and 82-95 are withdrawn.

#### Double Patenting Rejections

In the Office Action, the Examiner rejected claims 1-20, 24-31, 35-37, 52-64, 68-75 and 79-81 under the judicially created doctrine of obviousness-type double patenting as being unpatentable in view of claims 1-85 of U.S Patent No. 6,838,484 or claims 1-10 of U.S. Patent No. 6,569,896 or claims 1-5 of U.S. Patent No. 6,492,554.

Applicants hereby offer to provide a terminal disclaimer upon indication by the Examiner of allowable claims.

#### CLAIM REJECTIONS

##### 35 U.S.C. § 103 Rejections

In the Office Action, the Examiner rejected claims 1-20, 24-31, 35-37, 52-64, 68-75 and 79-81 under 35 U.S.C. § 103(a), as allegedly being rendered obvious in view of combined teaching of Tucker (US 4,636,505) and Miller et al (WO 98/55153). Applicants disagree.

Claims 1, 52, 69, and dependents therefrom are directed to metabolites of O-bridged SARM compounds represented by formulas I, II, III, IV, VII, VIII, IX, X. The metabolites of compounds of formulas I, II, III, IV, VII, VIII, IX, X, are produced as a result of *in-vivo* metabolic processing of the compounds, to yield, *inter-alia*, oxidized, hydroxylated, glucuronidated, hydrolyzed, and methylated forms of the compounds of formulas I, II, III, IV, VII, VIII, IX, X.

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Miller does not describe nor provide any foundation for metabolites of such SARMs. Specifically Miller describes radiolabelled SARMs only, and their use in imaging the prostate cancer, alone, with only S-bridged compounds exemplified in this context. It would not be obvious, based on Miller, to obtain claimed metabolites of O-bridged compounds of this invention, as one skilled in the art would not be motivated to obtain unlabelled metabolites to image prostate cancer.

Similarly, Tucker neither describes nor provides any foundation for metabolites of such SARMs. Tucker describes a laundry list of antiandrogenic compounds, with only the process of preparation of S-bridged compounds are exemplified. It would not be obvious based on Tucker that the metabolites of O-bridged compounds have androgenic and anabolic activity.

Tucker nor Miller provides any guidance for preparing SARM metabolites. Thus, neither Miller nor Tucker, alone or in combination, render obvious the O-bridged metabolite including *inter-alia* oxidized, hydroxylated, glucuronidated, hydrolyzed, and methylated forms of the compounds of formulas I, II, III, IV, VII, VIII, IX, X, as claimed in the present invention. Accordingly, applicants request withdrawal of the rejection.

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

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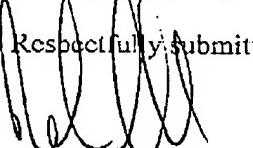
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Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,

  
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